# 

# Submission of information on

Evidence to support the substitution of formaldehyde with hydrogen peroxide in PTs 2 & 3

**non-confidential**

**Legal name of submitter(s):** Withheld

Table of CONTENTS

1. alternative IDentity and properties 3

2. Technical feasibility 3

3. Economic feasibility 4

4. Hazards and risks of the alternative 4

5. Availability 4

6. Conclusion on suitability and availability of the Alternative 4

7. other comments 5

References 5

# alternative IDentity and properties

Hydrogen Peroxide

EC number: 231-765-0

CAS number: 7722-84-1

Molecular formula: H2O2

Physical state: Liquid

Odour: Odourless

Substance type: Inorganic

Hydrogen peroxide is an oxidising agent

This recommendation is for the substitution of Formaldehyde with Hydrogen peroxide ≤35% for the disinfection of enclosures, such as biological safety cabinets, laboratories, isolators, rooms, etc.

Classification & labelling: The following hazard statements apply -

H302 – Harmful if swallowed

H332 – Harmful if inhaled

H315 – Causes skin irritation

H318 – Causes serious eye damage

H335 – May cause respiratory irritation

Signal word: DANGER

Efficacy of the alternative:

Hydrogen peroxide vapour has been used as an accepted alternative to Formaldehyde fumigation for over a decade. The efficacy of hydrogen peroxide vapour has been independently proven against a wide variety of microbiological organisms (see references). Comparative assessments of formaldehyde based decontamination versus hydrogen peroxide vapour based decontamination have been conducted in a variety of enclosures. References to these studies are provided.

Measures to protect humans, animals and the environment:

Hydrogen peroxide vapour is produced and applied via an automated system located within the sealed target enclosure. Humans and animals are excluded from the enclosure during the decontamination process, eliminating exposure risks. Post microbiological deactivation, the hydrogen peroxide vapour is catalytically converted to oxygen (O2) and water (H2O), leaving no residue or environmental contaminants.

# Technical feasibility

Hydrogen peroxide vapour generators are available on the market to allow for the replacement of formaldehyde in enclosure decontamination without the need to modify existing enclosures. Personnel will require re-training in the use of hydrogen peroxide vapour application equipment. However, hydrogen peroxide vapour based enclosure decontamination can be procured as a service eliminating the requirement for user training. Validation of existing disinfection / sterilisation processes may be required. Biological indicators and chemical indicators are widely available to measure process performance and facilitate decontamination cycle validation. Electronic detectors are available to monitor hydrogen peroxide levels and enclosure leak integrity.

# Economic feasibility

The cost of hydrogen peroxide vapour distribution systems are higher than formaldehyde fumigation systems. The costs of hydrogen peroxide consumables (hydrogen peroxide solution) are higher than Formaldehyde solutions.

Formaldehyde fumigation cycle times are longer than equivalent hydrogen peroxide vapour cycle times, particularly if a Formaldehyde quench (such as ammonia) is not employed (see references, Lin et al). As such, enclosure “out-of-service” times are longer for Formaldehyde fumigation with higher associated costs. Post disinfection cleaning of the Formaldehyde residues must also be taken into consideration, whereas hydrogen peroxide vapour is residue free. A review by Nottingham University, UK (2012) suggests that when the down-time and clean-up costs of formaldehyde fumigation of a biological safety cabinet are included, formaldehyde fumigation may be more expensive than a hydrogen peroxide vapour based service.

# Hazards and risks of the alternative

Formaldehyde has been classified as a carcinogenic agent by the International Agency for Research on Cancer (IARC). Hydrogen peroxide vapour has no such classification.

Hydrogen peroxide vapour is an oxidiser and corrosive agent. However, good quality hydrogen peroxide vapour application systems are designed to ensure users do not come into contact with the chemical, through the use of sealed consumable packaging and removal of the vapour (via catalytic conversion to oxygen and water) once the decontamination is complete. The breakdown of the hydrogen peroxide to oxygen and water removes environmental contamination risks.

Transfer of enclosure decontamination from Formaldehyde based to hydrogen peroxide vapour based has been occurring over the past decade, primarily due to the carcinogenic concerns associated with formaldehyde. The risks to human health and the environment are reduced through the use of hydrogen peroxide vapour versus Formaldehyde.

# Availability

Hydrogen peroxide vapour and its application systems are widely available across Europe from a number of suppliers including:

Steris

Bioquell

# Conclusion on suitability and availability of the Alternative

The transition from Formaldehyde based enclosure decontamination to hydrogen peroxide vapour based decontamination has been underway within the market for many years, due to the health and safety concerns associated with Formaldehyde. Official substitution of Formaldehyde with hydrogen peroxide vapour is a logical progression.

# other comments

This recommendation for substitution of Formaldehyde specifically relates to the use of hydrogen peroxide vapour systems, not hydrogen peroxide aerosol systems (often referred to as foggers or dry-mist systems). The efficacy of hydrogen peroxide vapour systems differ from hydrogen peroxide aerosol systems, as can be seen in the study by Beswick et al (see references). This study also compares the efficacy of a range of alternative decontamination agents to Formaldehyde. Although the efficacy of Formaldehyde is reported to be superior in this study, the authors recognise the human health risks associated with its use and the need for it to be substituted.

# References

Beswick, A.J., Farrant, J., Makison, C., et al. 2011. Comparison of multiple systems for laboratory whole room fumigation. *Applied Biosafety*. Vol 16, No 3, p139-157.

Bioquell. Hydrogen peroxide vapour (HPV) biological efficacy. (<http://www.bioquell.com/files/6314/1131/1578/HPV_Biological_Efficacy.pdf> )

Cogliano, V.J., Grosse, Y., Bann, R.A., et al. 2005. Meeting report: Summary of IARC Monographs on Formaldehyde, 2-Butoxyethanol, and 1-tert-Butoxy-2-Propanol. *Enviro. Health Perspectives*. Vol 113, No 9, p1205-1208

Jia, H.Q., Li, Y.J., Sun, B., et al. 2013. Evaluation of vaporized hydrogen peroxide fumigation as a method for the biodecontamination of the high efficiency particulate air filter unit. *Biomed. Environ. Sci.* Vol 26, No 2, p110-117.

Kahnert, A., Seiler, P., Stein, M., et al. 2005. Decontamination with vaporized hydrogen peroxide is effective against Mycobacterium tuberculosis. *Letters in Applied Microbiology*. Vol 40, p448-452.

Krishnan, J., Berry, J., Fey, G., et al. 2006. Vaporized hydrogen peroxide-based biodecontamination of a high containment laboratory under negative pressure. *Applied Biosafety*. Vol 11, No 2, p74-80.

Lin, X.Q., Atmadi, A., and Nelson, O. Decontamination of ESCO Class II biological safety cabinet using vaporized hydrogen peroxide. ESCO Technologies Incorporated (<http://www.escoglobal.com/resources/pdf/hydrogen_peroxide_decon.pdf> )

Maris, P. 2012. Is airborne surface disinfection using hydrogen peroxyde an alternative to formaldehyde? *Euroreference*, No 6, ER06-12M02.

University of Nottingham Safety Office (UK). 2012. Policy for the choice of fumigant for fumigation of microbiological safety cabinets and containment level 3 suites. (<https://www.nottingham.ac.uk/safety/documents/bio-msc-fumigant-selection.pdf> )